McNeil
Consumer & Specialty Pharmaceuticals

DEC 2 0 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject: Docket OOD-1538
McNeil Comments to FDA Draft Guidance for Industry on 21CFR Part 11; Electronic Records; Electronic Signatures - Validation

Dear Sir or Madam:

McNeil Consumer & Specialty Pharmaceuticals (McNeil) submits the following comments on the proposed "Draft Guidance for Industry on 21CFR Part 11; Electronic Records; Electronic Signatures – Validation". For ease of review, they are provided in tabular format beginning on the following page.

Overall comment on this guidance is that this document does not appear to provide any new guidance regarding validation in general and specifically on Part 11 Validation. All validation issues applicable to Part 11 have been discussed in previous validation guidelines published by the FDA.

If you have any questions regarding the attached comments, please do not hesitate to contact me at (215) 273-8733.

Sincerely,

McNeil Consumer & Specialty Pharmaceuticals

Maureen M Barrow for

Jacqueline U. Linse
Director, Global Submissions and
CMC Regulatory

OOD-1538 C 14

FDA Validation Guidance	Comment	Suggestion
Section 2.1 "Applicability" This draft guidance applies to electronic records and electronic signatures that persons create, modify, maintain, archive, retrieve, or transmit under any records or signature requirement set forth in the Federal Food, Drug, and Cosmetic Act (the Act), the Public Health Service Act (PHS Act), or any FDA regulation. Any requirements set forth in the Act, the PHS Act, or any FDA regulation, with the exception of part 11, are referred to in this document as predicate rules. Most predicate rules are contained in Title 21 of the Code of Federal Regulations. In general, predicate rules address the research, production, and control of FDA regulated articles, and fall into several broad categories. Examples of such categories include, but are not limited to: manufacturing practices, laboratory practices, clinical and pre-clinical research, adverse event reporting, product tracking, and pre and post marketing submissions and reports.	"Predicate rule" already defined in the draft Glossary of Terms. No need to repeat definition.	This draft guidance applies to electronic records and electronic signatures that persons create, modify, maintain, archive, retrieve, or transmit under any records or signature requirement set forth applicable predicate rules.
Section 5.1, "System Requirements Specifications"	The word "Specifications" is incorrectly used throughout the document. Refer to definition (below) contained in the FDA Glossary of Computerized Systems **Definition:** A specification (IEEE) is a document that specifies, in a complete, precise, verifiable manner, the requirements, design, behavior, or other characteristics of a system or component, and often, the procedures for determining whether these	System Requirements or System Requirements Specification

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	provisions have been satisfied. Contrast with requirement. See: specification, formal; specification, requirements; specification, functional; specification, performance; specification, interface; specification, design; coding standards; design standards.	
Second sentence, Section 5.2.3, "Validation Report"	The section covers the validation report. The second sentence refers to test results. The subject of how to report test results is discussed in Section 5.4.3.	Second sentence in Section 5.2.3 should be deleted and moved to Section 5.4.3.
First bullet, Section 5.4.2 , "Software testing should include"	The main section, Section 5.4, refers to "Dynamic Testing." First bullet is more consistent with Section 5.5, "Static Verification Techniques"	Delete bullet from Section 5.4.2 and add information to Static Verification, Section 5.5.
Section 5.6, "Extent of Validation"	To keep the flow of the document, this section should be move to the beginning of the document.	Section 5.6 should be moved before Section 5.3.
Section 5.7 "Independence of Review"	Guidance documents tend to be interpreted as policy/procedures-As such, emphasis will most likely be placed on option one by various enforcement organizations.	Delete lines 160 through 162 (Two approaches to ensuring an objective review…)
Section 6.1.1, "End User Requirements Specifications"	The issues discussed in this section, were discussed in Section 5.1	Move Section 6.1.1 to 5.1 or vice versa.

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	Also: The statement "if possible, the end user should obtain a copy of the developer's requirement specification for comparison". It is highly unlikely that any software vendor would share their requirements documents. Since they are such an important work product in the development of software, they would be considered confidential, proprietary and a key source of competitive advantage for the software company.	Delete statement recommending to obtain developer's requirement specification.
6.1.2 Software structural integrity	This entire section deals with what to do with commercial software and how to evaluate it for structural integrity when source code is not available. Source code will almost never be available for review from a commercial software vendor. It may be possible, though difficult, to convince a software vendor to show records of all of their software problems. However, it is unlikely that the purchasor of the software will be able to infer the structural integrity of the software from looking at these records. While it is logical to evaluate a business function application software with a software developer audit (such as BBN/Domain Clintrial or Documentum), it seems that certain	Delete item (3) regarding identification of known problems. This should be covered under section (1) and (2) and if not, it is unlikely that a vendor will provide that information. Provide for exemptions from auditing for widely used software programs which have become de facto industry standards, rather, describe use testing to demonstrate applicability for intended purpose.

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	widely used software packages could be exempted from this requirement. An example would be Microsoft WORD or EXCEL. It seems excessive to perform vendor audits on such widely used products.	
6.2.1 Internet Validation	In the last sentence of this section they explain how to validate internet communications. It is not clear that sending faxes or voice messages, or phone calls is required only during validation testing. If it is required for ongoing use of internet communications (such as daily transmission of clinical study data) then the value of automation is eliminated.	Clarify that sending faxes or voice messages or phone calls is required only during validation testing.